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Docket No. ENT/4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Anita H. Lewin et al.

Application No.: 10/646,284 Confirmation No. : 9373

Filed : August 21, 2003

For : METHODS FOR PRODUCING HYDROXYALKYL
TROPANE ESTERS

Group Art Unit : 1625

Examiner : Not yet assigned

New York, New York
June 3, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR
INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith are an Information
Disclosure Statement, Form PTO-1449, and copies of
references cited therein in the above-identified
application. This Statement is submitted:

[] within three months of the application filing date;

[X] more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

Michele A. Kercher

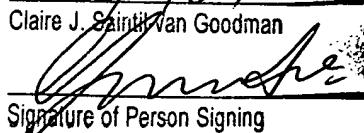
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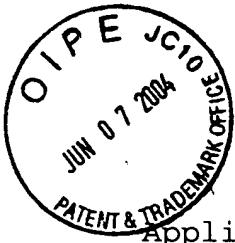
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Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants, through their representatives, make of record the following documents.*

United States Patents

<u>Inventor</u>	<u>Patent No.</u>	<u>Issue Date</u>
Somers et al.	5,663,345	September 2, 1997
Somers et al.	5,559,123	September 24, 1996

* A complete Form PTO-1449 listing these documents is attached hereto.

Somers et al.	5,376,667	December 27, 1994
Somers	4,556,663	December 3, 1985
Somers	4,512,996	April 23, 1985
Somers	4,469,700	September 4, 1984
Rudner et al.	2,948,730	August 9, 1960
Rudner et al.	2,893,996	July 7, 1959

OTHER DOCUMENTS

W.H. Anderson and D.T. Stafford, "Applications of Capillary Gas Chromatography in Routine Toxicological Analyses", J. High Resolut. Chromatogr., Chromatogr. Commun., 6, pp. 247-254 (1983)

M.R. Bell and S. Archer, "L(+) -2-Tropinone", J. Amer. Chem. Soc., 82, pp. 4642-4644 (1960)

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G. Werner and K.H. Störr, "Labelled Tropane Alkaloids. VI. Synthesis of [N-methyl-T1] Psicain-nue and of Polytopically Tritiated Psicain", Liebigs Ann. Chem., pp. 1650-1654 (1974)

J.J. Woodward et al., "Cocaethylene Inhibits Dopamine Uptake and Produces Cocaine-Like Actions in Drug Discrimination Studies", Eur. J. Pharmacol., 197, pp. 235-236 (1991)

I. Zimányi et al., "Effect of Cocaine and Cocaine Congeners on Veratridine-Induced Depolarization in Mouse Cerebrocortical Synaptoneuroosomes", J. Neurosci. Res., 22, pp. 201-208 (1989)

Some of the documents listed above were cited in an International Search Report issued in connection with PCT application PCT/US03/26433 from which the present application claims priority. For the convenience of the Examiner, a copy of the Search Report is attached.

Applicants respectfully request that these documents be (1) considered by the Examiner prior to issuance of any

patent from this application; and (2) printed on any patent that may issue from this application. Applicants also request that a copy of enclosed Form PTO-1449, as considered and initialed by the Examiner, be returned with the next communication.

This Statement is submitted more than three months from the application filing date but before the mailing date of the first Office Action on the merits. In accordance with 37 C.F.R. § 1.97(b) (3), submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this Statement is transmitted herewith.

Respectfully submitted,

Michele A. Kercher

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Nina R. Horan (Reg. No. 47,662)
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Michele A. Kercher (Reg. No. 51,869)
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FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. ENT/4	APPLN. NO. 10/646,284
O I P E JC10 JUN 01 2004 PATENT & TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT Anita H. Lewin et al.	CONFIRMATION NO. 9373
		FILING DATE August 21, 2003	GROUP 1625

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

	5,663,345	09/02/97	Somers et al.	546	127	
	5,559,123	09/24/96	Somers et al.	514	304	
	5,376,667	12/27/94	Somers et al.	514	304	
	4,556,663	12/03/85	Somers	514	304	
	4,512,996	04/23/85	Somers	514	304	
	4,469,700	09/04/84	Somers	424	265	
	2,948,730	08/09/60	Rudner et al.	260	292	
	2,893,996	07/07/59	Rudner et al.	260	292	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
	W.H. Anderson and D.T. Stafford, "Applications of Capillary Gas Chromatography in Routine Toxicological Analyses", <u>J. High Resolut. Chromatogr.</u> , <u>Chromatogr. Commun.</u> , 6, pp. 247-254 (1983)
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	R.M. Smith, "Ethyl Esters of Arylhydroxy- and Arylhydroxymethoxycocaines in the Urines of Simultaneous Cocaine and Ethanol Users", <u>J. Anal. Toxicol.</u> , 8(1), pp. 38-42 (1984)
	D.L. von Minden and N.A. D'Amato, "Simultaneous Determination of Cocaine and Benzoylecgonine in Urine by Gas-Liquid Chromatography", <u>Anal. Chem.</u> , 49(13), pp. 1974-1977 (1977)
	G. Werner and K.H. Störr, "Labelled Tropane Alkaloids. VI. Synthesis of [N-methyl-T1] Psicain-nue and of Polytopically Tritiated Psicain", <u>Liebigs Ann. Chem.</u> , pp. 1650-1654 (1974)

EXAMINER

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